DATA EVALUATION RECORD
§ 72-1 - ACUTE LC_{50} TEST WITH A COLDWATER FISH

1. **CHEMICAL:** Metolachlor PC Code No.: 108801

2. **TEST MATERIAL:** CGA-51202 Purity: Not reported

3. **CITATION:** Author: A. Vial
   Title: Report on the Acute Toxicity Test of CGA-51202 to Rainbow Trout (*Onchorhyncus mykiss*)
   Study Date: August 12, 1991
   Laboratory: Ciba-Geigy Limited, Crop Protection Division, Basle, Switzerland
   Sponsor: Novartis Crop Protection, Inc., Greensboro, NC
   Laboratory ID: 918150
   MRID No.: 449295-01
   DP Barcode: D260006

4. **REVIEWED BY:** Karl Bullock, M.S., Environmental Scientist,
   Golder Associates Inc.
   Signature: **Date:**

   APPROVED BY: Pim Kosalwat, Ph.D., Senior Scientist,
   Golder Associates Inc.
   Signature: **Date:**

5. **APPROVED BY:** Brian Montague, Fisheries Biologist
   Environmental Fate and Effects Division, OPP
   Signature: Brian Montague **Date:** March 2000

6. **STUDY PARAMETERS:** **Age or Size of Test Organism:** Mean: 57 mm
   Definitive Test Duration: 96 hours
   Study Method: Static
   Type of Concentrations: Mean measured

7. **CONCLUSIONS:** This study is scientifically sound but does not fulfill Agency guideline requirements for an acute toxicity test with the rainbow trout. The 96-hour LC_{50} was determined to be >100 ppm nominal (>96.3 ppm mean measured concentration), which classifies CGA-51202 as practically non-toxic to the rainbow trout. The NOEC was 100 ppm nominal (96.3 ppm mean measured concentration).

   Results Synopsis

LC_{50}: >100 ppm (>96.3 ppm mean measured)	95% C.I.: N/A	
	NOEC: 100 ppm	Probit Slope: N/A

8. **ADEQUACY OF THE STUDY:**
   - **A. Classification:** Invalid
   - **B. Rationale:** The purity of the test substance was not reported. De-chlorinated water was employed.
   - **C. Repairability:** No

9. **GUIDELINE DEVIATIONS:**

1. The percent purity of the test substance was not reported.
2. Dilution water was dechlorinated tap water.
3. Temperature was not measured continuously as recommended by the guidelines. The test temperature (14°C) was greater than recommended (12°C).
4. Pretest mortality was not reported.
5. Test solutions were aerated during the test.

10. **SUBMISSION PURPOSE:** Submitted to support registration of metolachlor products.

11. **MATERIALS AND METHODS:**

A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species is the rainbow trout (*Oncorhynchus mykiss*)	*Oncorhynchus mykiss*
Mean Weight 0.1-5 g	Mean: 1.71 g Range: 1.02-2.50 g
Mean Standard Length Longest not > 2x shortest	Mean: 57 mm Range: 50-63 mm
Supplier	P. Hohler/CH-4314 Zeiningen
All fish from same source?	Yes
All fish from the same year class?	Not reported

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period Minimum 14 days	48 days
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	Not reported
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	Fish were treated with 0.15 mg malachite green/L for 5 hours on April 6, 1991, approximately 6 weeks before test initiation.
Feeding No feeding during the study	Last fed 24 hours prior to testing
Pretest Mortality < 3% mortality 48 hours prior to testing	Not reported

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, **not** dechlorinated tap water	Carbon filtered, dechlorinated tap water.
Does water support test animals without observable signs of stress?	Yes
Water Temperature 12°C	14°C
pH Prefer 7.2 to 7.6	7.6 - 8.3
Dissolved Oxygen Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs, flow-through: ≥ 60%	≥90% during the test

Guideline Criteria	Reported Information
Total Hardness Prefer 40 to 200 mg/L as $CaCO_3$	164 mg/L as $CaCO_3$
Test Aquaria 1. Material: Glass or stainless steel 2. Size: Volume of 18.9 L (5 gal) or 30 x 60 x 30 cm 3. Fill volume: 15-30 L of solution	 Glass 20 L 15 L
Type of Dilution System Must provide reproducible supply of toxicant	Not reported but test assumed to be static test.
Flow Rate	Not applicable if static test
Biomass Loading Rate Static: ≤ 0.8 g/L at ≤ 17°C, ≤ 0.5 g/L at > 17°C; flow-through: ≤ 1 g/L/day	0.57 g/L
Photoperiod 16 hours light, 8 hours dark	16 h light, 8 h dark
Solvents Not to exceed 0.5 mL/L for static tests or 0.1 mL/L for flow-through tests	Solvent: none Maximum conc.: N/A

D. Test Design

Guideline Criteria	Reported Information
Range Finding Test If LC_{50} >100 mg/L with 30 fish, then no definitive test is required.	Pretests were conducted, but the results were not reported.

Guideline Criteria	Reported Information
Nominal Concentrations of Definitive Test Control & 5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be in a geometric series	Negative control, 10, 18, 32, 58, and 100 mg/L, not corrected for percent purity.
Number of Test Organisms Minimum 10/level, may be divided among containers	10 fish per treatment level or control, 5 per replicate
Test organisms randomly or impartially assigned to test vessels?	Not reported
Biological observations made every 24 hours?	Yes
Water Parameter Measurements 1. Temperature Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1 °C 2. DO and pH Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	Temperature, DO, and pH were measured daily in each test chamber.
Chemical Analysis Needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not steel or glass, or if flow-through system was used	Samples were collected from each test vessel at test initiation and termination for analysis.

12. REPORTED RESULTS:

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes, however, the compliance was with OECD and Swiss GLP.
Recovery of Chemical **1.** Mean recovery **2.** Detection limit **3.** Method validation	1. 91-99% of nominal 2. <1.0 mg/L 3. 108% of nominal
Control Mortality Not more than 10% control organisms may die or show abnormal behavior.	0% mortality in control
Raw data included?	Yes
Signs of toxicity (if any) were described?	No signs of test material toxicity were observed.

Analytical Results

Toxicant Concentration (mg/L)				
Nominal	Hour of Study		Mean Measured (SD)	Percent of Nominal
	0	96		
Control	<1	<1	-	-
10	9.90	8.30	9.10 (1.1)	91
18	17.80	16.70	17.3 (0.8)	96
32	29.10	29.20	29.2 (0.1)	91
58	57.10	57.20	57.2 (0.1)	99

100	98.60	93.90	96.3 (3.3)	96

Mortality

Concentration (mg/L)		Number of Fish	Cumulative Number Dead			
Nominal	Mean Measured		Hour of Study			
			24	48	72	96
Negative Control	<0.10	10	0	0	0	0
10	9.10	10	0	0	0	0
18	17.3	10	0	0	0	0
32	29.2	10	0	0	0	0
58	57.2	10	0	0	0	0
100	96.3	10	0	0	0	0

Other Significant Results: No sublethal signs of test material toxicity were observed.

B. Statistical Results

Statistical method: Visual observation using nominal concentrations

LC_{50}: >100 mg/L 95% C.I.: N/A

Probit Slope: N/A NOEC: 100 mg/L

13. VERIFICATION OF STATISTICAL RESULTS:

Parameter	Result
Binomial Test LC_{50} (95% C.I.)	N/A
Moving Average Angle LC_{50} (95% C.I.)	N/A

Probit LC_{50} (95% C.I.)	N/A
Probit Slope	N/A
NOEC	100 ppm

14. **REVIEWER'S COMMENTS:** This study is scientifically sound but does not fulfill the EPA criteria requirements for a fully acceptable acute toxicity test with the rainbow trout. The percent active ingredient of the test substance was not reported and de-chlorinated tap water was employed. Several other omissions of data regarding test organisms and test methods were also noted. Based on nominal concentrations, the 96-hour LC_{50} was determined to be >100 ppm (>96.3 ppm mean measured concentration), which classifies CGA-51202 as practically non-toxic to the rainbow trout. The NOEC was 100 ppm (96.3 ppm mean measured concentration). This study is classified as **invalid**.

PAGES 9 THROUGH 15 HAVE BEEN REMOVED FROM THIS COPY. THOSE PAGES CONSIST OF REGISTRANT-SUBMITTED DATA